

SEP - 7 2000

K001342

**510(k) Summary**

1. **Submitter:** Post Operative Pain Management (Inc) LLC  
1 Corporation Center  
Broadview Heights, OH 44147  
  
Tel: 440-526-5104  
Fax: 440-526-0158
2. **Contact:** Charles Rowland II  
Regulatory Affairs and Product development  
Post Operative Pain Management (Inc) LLC
3. **Date Prepared:** April 27, 2000
4. **Device Trade Name:** P.O.P. Kit  
**Common Name:** Various
5. **Predicate Device(s)** Sgarlato PCIP (K896422)  
Pain Buster (K980558)
6. **Description** The P.O.P.™ Kit is a group of products that function as a system for the administration of pain medication directly into a surgical wound.
7. **Intended Use**
  - A) Sole use is for the administration of pain medication subcutaneously.
  - B) For use up to 24 hours or institutional protocol.
  - C) For single patient use.
8. **Comparison to predicate device(s)**

The P.O.P.™ Kit offers identical technique, usage parameters and intended use to the predicate device(s). The elastomeric membrane delivers fluid at a controlled rate and manner the same as the Predicate devices.
9. **Non-clinical Test Summary**

All kit components are currently individually available for distribution via 501(k).
10. **Conclusion**

The P.O.P.™ Kit is substantially equivalent to the products currently being legally marketed by Sgarlato Labs and I-Flow Corporation.

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## **SUMMARY OF SAFETY AND EFFECTIVENESS**

**April 27, 200**

**Trade Name:** P.O.P. Post Operative Pain Kit

**Common Name:** Elastomeric Infusion Pump Kit

**Classification Name:** Pump, Infusion, Elastomeric

**All questions and/or comments concerning this document should be made to:**

**Charles Rowland II  
Regulatory Affairs and Product Development**

**Post Operative Pain Management (Inc.) LLC  
1 Corporation Center  
Broadview Heights, OH 44147**

**Telephone: 440-526-5104  
Fax: 440-526-0158**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP - 7 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Charles Rowland II  
Regulatory Affairs and Product Development  
Post Operative Pain Management, Incorporated  
One Corporation Center  
Broadview Heights, Ohio 44147

Re: K001342  
Trade Name: P.O.P Pain Kit  
Regulatory Class: II  
Product Code: MEB  
Dated: July 31, 2000  
Received: July 31, 2000

Dear Mr. Rowland:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

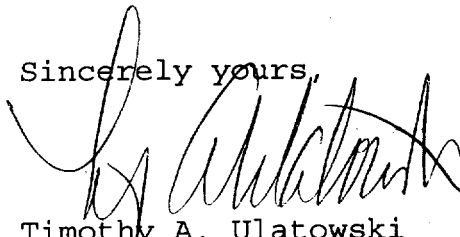
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director

Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K001342

DEVICE NAME : P.O.P. Pain Kit

INDICATIONS FOR USE:

Indications:

The system is indicated for the relief of pain by the administration of analgesics into the intra-operative site.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use X

OR

Over-The-Counter-Use \_\_\_\_\_

(Per 21 CFR 801.109)

(Optional Format 1-2)

Grantha B. B. B.

(Division Sign-Off)

Division of Dental, Infection Control,

and General Hospital Devices

Number K001342